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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/011,977	06/15/98	AMMON H	015200-054

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1623	6

DATE MAILED: 02/17/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/011,977	Applicant(s) Ammon et al.
	Examiner Howard Owens	Group Art Unit 1623

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *10-16* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *10-16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Specification

The specification does not conform to the preferred arrangement of a patent application for prosecution in front of the United States Patent and Trademark Office. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated below.

(a) Title of the Invention.
(b) Cross-References to Related Applications (if any).
© Statement as to rights to inventions made under Federally-sponsored research and development (if any).
(d) Background of the invention.
1. Field of the Invention.
2. Description of the Related Art including information disclosed under 37 C.F.R. §§ 1.97-1.99.

(e) Summary of the Invention.
(f) Brief Description of the Drawing.
(g) Description of the Preferred Embodiment(s).
(h) Claim(s).
(I) Abstract of the Disclosure.

Abstract Missing

This application does not contain an Abstract of the Disclosure as required by 37 C.F.R. § 1.72(b). An Abstract on a separate sheet is required.

References cited in the International Preliminary Examination Report should be provided on an appropriate 1449 for consideration and to fulfill applicants' duty to disclose for compliance with conventional U.S. practice.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for combating pulmonary emphysema, acute respiratory distress syndrome, shock

lung, cystic fibrosis, chronic bronchitis, glomerulonephritis or rheumatoid arthritis, does not reasonably provide enablement for the prevention of tumors and neoplasms as broadly asserted. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 11 is drawn to a method of preventing and/or combating pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis,rheumatoid arthritis tumors and neoplasms in a mammal by administering an effective amount of boswellic acid, a physiological acceptable salt, a derivative, a salt of the derivative or a plant preparation containing boswellic acid.

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in In re Wands 8USPQ 2d 1400. The factors include:

1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art,
7) breadth of the claims and the
8) level of skill in the art.

Quantity of experimentation necessary,Amount of guidance presented, Presence or absence of working examples

Applicant provides guidance for the treatment of symptoms associated with the disease states of pulmonary emphysema, acute

respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis or rheumatoid arthritis through. Applicant incorporates by reference evidence that given that plasmin may activate growth factors which can stimulate the reproduction of tumors, inhibition of plasmin activity may possibly inhibit the growth and metastatic spread of many kinds of cancer. Inhibition of plasmin activity however, would not guarantee a prevention of neoplasms. Given that these neoplasms or tumors are a cellular malignancy whose unique characteristic - loss of normal controls - results in unregulated growth, lack of differentiation, and ability to invade local tissues and metastasize.

Applicant however provides no guidance or sets forth sufficient examples to substantiate the prevention of a neoplasm given that the art does not support conclusively the prevention of a broad class of neoplasms; furthermore, for any assertion to neoplasms or tumors broadly, there should be an adequate written description which teaches how to use the instant active ingredient(s) in methods which substantiate that the claimed therapeutic compounds have efficacy as broadly asserted for preventing neoplasms.

Applicant's references to a mammalian organism in need is seen to include all mammalian organisms, including healthy mammalian organisms. All mammalian organisms are in need of preventing neoplasms, pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis and rheumatoid arthritis. No support is given for administering the active agent to a healthy mammalian organism and preventing onset of specific disease states, specifically neoplasms, pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis and rheumatoid arthritis.

State of the Prior Art

While the prior art is replete with examples of anticancer activity associated with boswellic acid or pentacyclic triterpenoid compounds, the art has not established a consistent therapeutic system which would enable prevention of a broad class of neoplasms.

Breadth of the Claims

Claim 11 is drawn to a method of preventing and/or combating pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis,rheumatoid arthritis tumors and neoplasms in a mammal by administering an effective amount of boswellic acid, a physiological acceptable salt, a derivative, a salt of the derivative or a plant preparation containing boswellic acid. Note applicant has broadly asserted the prevention of neoplasms and tumors.

Level of Skill in the Art

The relative skill in the art of formulating and determining methods for antineoplastic compounds, treatment of humans and mammals with neoplasms, is that of a Ph.D. and or M.D. Although the art has established the usefulness of boswellic acid or pentacyclic triterpenoid compounds in the treatment of cancer, there is not seen adequate support for the prevention of a broad spectrum of neoplasms or tumors by these compounds or compositions as broadly asserted;

The relative skill in the art of formulating and determining methods for antineoplastic compounds, treatment of humans and mammals with neoplasms, is that of a Ph.D. and or M.D. Although the art has established the usefulness of boswellic acid or pentacyclic triterpenoid compounds in the treatment of cancer, there is not seen adequate support for the prevention of a broad spectrum of neoplasms or tumors by these compounds or compositions as broadly asserted; thus claims drawn to the prevention of these neoplasms as broadly asserted should set forth therapeutic dosages or ratios in combination with other therapeutic agents. The specification also fails to teach how to use the instantly claimed compounds or compositions in the treatment of neoplasms singularly or in combination with other well known, art recognized means of treatment such as the use of additional chemotherapeutic agents simultaneously or in tandem which would provide prevention of a neoplasm or tumor in a human or mammal.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "chemically pure" in claim 16 is a relative term which renders the claim indefinite. The term "chemically pure" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "substance" in claim 16 renders the instant claim indefinite as applicant has failed to set forth with distinction what substance is claimed in conjunction with the boswellic acid, given the multitude of compounds and extracts that could be encompassed by the indiscriminate term "substance".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 10-16 are rejected under 35 U.S.C. § 103 as being unpatentable over Taneja et al., U.S. Patent No., 5,629,351 in view of Lee et al., U.S. Patent No. 5,064,823 and Patwardhan et al., U.S. Patent No. 5,494,668.

Claims 10-16 are drawn to a method of treating diseases in a mammal which are caused by increased leucocytic elastase or plasmin activity or can be treated by the inhibition of normal leucocytic elastase or plasmin activity by administering an effective amount of boswellic acid, a physiological acceptable salt, a derivative, a salt of the derivative or a plant preparation containing boswellic acid. Wherein the diseases are pulmonary emphysema, acute respiratory distress syndrome, shock lung, cystic fibrosis, chronic bronchitis, glomerulonephritis, rheumatoid arthritis tumors and neoplasms.

Taneja teaches the use of antiinflammatory, antiarthritic and antiulcerogenic activity of boswellic acids. However, Taneja does not disclose the anticancer properties of boswellic acid (col. 4,line 3 - col. 5, line 5).

Lee et al. disclose treating various cancers in mammals by the administration of pentacyclic triterpenoid compounds such as boswellic acid(s) (see abstract and col. 10, lines 28-45).

Patwardhan teaches a method of treating degenerative musculoskeletal diseases such as rheumatoid arthritis and osteoarthritis in an animal, typically a human, typically enterally, comprising administering in a convenient dosage form an effective amount of several plant extracts including boswellic acid (see abstract and col. 3, line 60 - col.6, line 42).

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the

discoverer as a process of using. However, when the claim recites using an old compound or composition and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated; moreover, a patentable compound or composition of matter is one that is produced by intermixture of two or more specific ingredients; and possesses properties pertaining to none of these ingredients separately, thereby accomplishing a new and useful result. In the case of the instant application, the use of boswellic acid or the general class of pentacyclic triterpenoid compounds (singularly or as a composition) is well documented in the art for anticancer, antiinflammatory and antiarthritic activities. Applicant has not obviated the prior art by incorporation of an inherent property of the boswellic acid, specifically the inhibition of normal leucocytic elastase or plasmin activity, into the method claim.

A *prima facie* case of obviousness is supported when the prior art alone would have appeared to suggest doing, at the time the invention was made, what the applicant has done. Given routine experimentation common to practice of an invention in any art, one of skill in the art would have been provided with a clear motivation and a reasonable expectation of success to use boswellic acid in a method for the treatment of disease states associated with inflammatory, arthritic or oncogenic diseases given the use of these compounds for the disease states cited supra in the prior art. Expected beneficial results are evidence of obviousness just as unexpected beneficial results are evidence of unobviousness.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens

whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

February 15, 1999

Howard Owens
Group 1623

JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600